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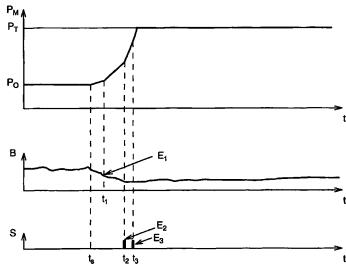
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(54) Title: APPARATUS TO ASSIST A PATIENT'S BREATHING WITH A VARIABLE RAMP PERIOD TO RISE TO TREAT-MENT PRESSURE



(57) Abstract: The invention concerns an apparatus (1) to assist a patient respiration by delivering air to a patient trough a mask (20), comprising wherein a ramp module (10) connected to a control unit (2) in order to provide the control unit with the value of pressure PM to settle at said mask (20), so that when said apparatus (1) starts functioning, the pressure progressively rises until the pressure of treatment PTi the apparatus (1) further comprising a comparator connected to the ramp module (10), at least one means for detecting the patient's breathing parameters and sending them to said comparator, so that the comparator is able to determine that an event (E₁, E₂ or E₃) occurs in patient's breathing and to send the corresponding data to the ramp module (10) which provides the control unit (2) with a value of pressure PM that will speed up with respect of time, so that the rise of pressure at patient's mask (20) is accelerated.



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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Apparatus to assist a patient's breathing with a variable ramp period to rise to treatment pressure

5 Technical field

This invention concerns the field of apparatus to assist a patient respiration and more specifically an apparatus bringing progressively to the pressure of treatment the air the patient is provided with.

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Background art

In many treatments apparatus are used to provide patients with air. More frequently they are used for patients with a breathing deficiency caused for example by the weakness of the breathing system or by obstructive apneas during the sleep. In those cases it is important to control the pressure of the air delivered to the patient. With respiratory insufficient patients, apparatus providing air at a higher pressure help to compensate the weakness of the patients lungs. In the case of patients suffering of sleep apneas, providing the air at a higher pressure removes the obstruction of the upper airways.

The pressure of treatment is usually not strong enough to wake the patient up, but can prevent him from falling asleep. An implementation of treatments apparatus is to wait for the patient to fall asleep before providing air under the treatment pressure. The classical solution is to have a ramp period, which is a slow increase of the delivered pressure from a low level to the treatment pressure.

Still to enhance the comfort of the patient, it is disclosed in patent US5,492,113 and US5,970,975 an apparatus wherein several cycles of ramp are provided on patient's conscious demand. The cycles actuated after the first cycle rise faster in pressure. All those ramps are

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predetermined in shape and duration. The patient can also select a fastest shape of ramp or select one special shape in order to fall asleep more easily. This selection being made among different predetermined shapes of ramp. However, such devices require from the patient a minimum of consciousness to activate the ramp cycles. This is not really very efficient to fall asleep and it is not possible when the patient as fallen asleep.

Moreover each ramp can not be modified during the time when the ramp is activated.

Summary of the invention

The first object of the invention is to provide a ramp that would be able to modulate automatically, especially when the patient falls asleep.

A second object of the invention is to provide in any case a maximum of time in rise of pressure, in order to apply the treatment in any case.

The invention thus concerns an apparatus to assist a patient respiration by delivering air to a patient trough a mask, comprising:

- a blower to provide the patient with air under a treatment pressure,
- a control unit to adjust the pressure delivered by the 25 blower at the level of the patient's mask,
 - a ramp module connected to the control unit in order to provide the control unit with the value of pressure P_M to settle at the mask, so that when the apparatus starts functioning, the pressure progressively rises until the pressure of treatment P_T ;
 - the apparatus comprising a comparator connected to the ramp module, means for detecting the patient's breathing parameters and sending them to said comparator, in order that in response to breathing parameters, the comparator is able to determine that an event occurs in patient's breathing and to send the corresponding data to the ramp module which provides the

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control unit with a value of pressure P_M that will speed up with respect of the time, so that the rise of pressure at patient's mask is accelerated.

In an implementation of the invention, the value of pressure P_M has always maximum and/or minimum limits so that the increase of pressure is also limited in minimum and/or maximum.

Such an apparatus has the advantage to generate a ramp period which can be modulated in the same ramp, according to patient's breathing parameters.

Brief description of figures

The purposes, objects and characteristics of the invention will become more apparent from the following description when taken in conjunction with the accompanying drawings in which:

Figure 1 represents the apparatus schema,

Figure 2 represents the pressure delivered to the patient's mask according to special events occurring in patient's breathing,

Figure 3 represents the domain of pressure increase, and Figure 4 represents the block diagram for the ramp period.

25 Detailed description of the invention

The apparatus according to the present invention is able to generate a ramp period which can be modulated in respect of the time required by the patient for falling asleep.

The apparatus as represented in figure 1 comprises a blower 4 to provide the patient with air. This blower is connected to a tube 8 on a first extremity, the second extremity being connected to the mask 20 wherein the patient breathes. A control unit 2 provides the blower 10 with the electrical control required to enable the blower to function in order to set a given pressure at the patient's mask or blower's outlet. This pressure could be by a pressure

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transducer 6 at the mask level or at the tube extremity, which is connected to the mask. A ramp module 10 is connected to the control unit 2 and to the pressure transducer 6. The ramp module provides the control unit 2 with the pressure at the patient's mask and with the pressure to settle at the patient's mask at the starting of the apparatus 1 functioning. During the treatment the control unit 2 is able to detect breathing events according to the pressure sensor 6 or any other way to evaluate or measure the patient's airflow. Such detection can be given by airflow sensors which provide the control unit with pressure parameters, the control units being thus able to detect that an event is occurring.

The apparatus according to the present invention is able to modulate the rise in pressure during one single ramp period, which is impossible to perform for apparatus of prior art. The apparatus comprises a ramp module 10 connected to the control unit 2 in order to provide the control unit with the value of pressure P_{M} to settle at the patient's mask, so that functioning, the pressure starts apparatus said progressively rises until the pressure of treatment $P_{\text{\tiny T}}$. The apparatus comprises a comparator which is not represented in figure1 and that can be comprised in the control unit 2. This comparator is connected to the ramp module 10. The apparatus comprise also at least one means for detecting the patients breathing parameters and sending them to said comparator, order that in response to said breathing parameters, comparator is able according to determine that an event occurs in patient breathing and to send the corresponding data to the ramp module which provide the control unit 2 with a value of pressure P_{M} that will speed up in respect of the time, so that the rise of pressure at patient's mask is accelerated.

According to a preferred embodiment, the ramp module 10 provides the value of pressure P_M being a linear function of time wherein the increase coefficient K_{RP} is constant, said ramp module increasing that coefficient of a constant value K_B

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when the control unit 2 send a data corresponding to the event which occurred.

In the apparatus 1 according to the present invention, a minimum speed of rise in pressure until the treatment pressure set, as represented by the curve C_2 on figure 3. This minimum rise of pressure in respect of time is called in the present application a safety ramp C_2 . Before the ramps period starts at the instant t_{s} , a minimum starting pressure P_{0} is delivered. After the instant t_{s} , even if the patient is not asleep, the pressure at the mask will start rising. In any case at the instant t_T , the treatment pressure will reached; this means that the curve C2 represents the minimum speed of rise in pressure. In a preferential implementation of the invention, the minimum speed of rise in pressure is proportional to time, the coefficient to rise in pressure according to time being K_{SR} . Also it can be set a maximum of rise in pressure as represented by the curve C_1 on figure 3. The maximum of rise in pressure can also be given a linear function of time. Between these two limits the rising of the pressure can be modulated by the control unit 2 in respect of the patient's falling asleep. That is to say that whenever any events occurs or not, the pressure provided at the patient's mask P_{PM} before the time of plain treatment t_T will comprised between these two limits, this domain of pressure variations being represented in figure 3 by the hachures.

When a patient is asleep his respiration becomes stable, this is used to detect the instant when the patient falls asleep. Another way to detect when the patient falls asleep is to detect the drop of frequency between the awake rate breathing and the awake breathing. As represented in figure 4 and according to a preferential implementation, the control unit 2 transmits the ramp module an output average pressure value P_M which is the pressure value required to patient's mask. When the patient is about to fall asleep, his respiration becomes stable. In that case the P_M value is increased, preferentially as a linear function of time, the

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proportional coefficient being K_{RP} . If the pressure value P_{M} is inferior to the safety ramp pressure P_{SR} , the pressure P_{M} is set to the value of the safety ramp pressure PSR, which is in a preferential implementation calculated by the module ramp 10 by multiplying the time spent from the beginning of the ramp routine to the present time by the coefficient Ksp. When the pressure value P_{M} equals or is superior to the treatment pressure P_{T} , the P_{M} pressure is maintained equal to the treatment pressure value P_T . On the contrary the control unit 2 checks again if the respiration is stable. This shows that until the patient falls as leep the P_{M} value will not be superior to the treatment pressure P_T , and will only equals it when the patient falls asleep or when the safety ramp reaches the treatment pressure value. This also shows that during the ramp period, if the respiration is stable, the air provided can rise faster than the safety ramp. In that case, coefficient K_{RP} will be higher than the coefficient K_{SP} . The ramp module will thus enable to the control unit to accelerate the rise in pressure when the patients fall asleep and when no events are detected.

An other implementation of the apparatus according to the present invention is that when the control unit detects an an event in patients breathing that shows an asleep state , the control unit will provide the ramp module 10 with the information. The ramp module will thus increase again the rise in pressure.

The following are examples of ramp periods generated by the apparatus according the present invention.

$\underline{\text{Example 1: Variations of value } P_{M}}$ according to different events

Figure 2 represents one example of the apparatus functioning wherein three systems of coordinates are represented: pressure value PM as a function of time, patient's breathing B as a function of time and snoring S as a function of time. At a time $t_{\rm S}$, the ramp module 10 activates

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the rise in pressure. At time t_1 as a slowdown E_1 in breathing is detected, the rise in pressure is accelerated by the ramp module 10. Then at time t2 snoring E2 is detected. Thus, the rise in pressure is accelerated again by the ramp module. As at time t_3 a snoring E_3 is still detected the ramp module still accelerates the rise in pressure. As represented on figure 2, the preferred embodiment is a linear in pressure. Thus at time t_s , the coefficient K_{RP} of rise in pressure is constant. Each time an event is detected the $K_{\mathbb{R}}$ given constant value module ramp adds a coefficient, the slope of the linear function being thus accentuated at each event. This will last until the treatment pressure P_T is raised. Then the ramp is completed and the control unit applies the treatment pressure to the patient's mask. The value $K_{\!\scriptscriptstyle\rm E}$ can be set by the physician in a non volatile memory and can be different according to the event detected.

Example 2 : Example of calculating the value P_M

In this example the treatment pressure P_T is of 10 hecto pascal (hPa). The initial pressure P_0 of the air provided at patient's mask is 4 hPa. A physician has set that the ramp will start at a time ts of 2 minutes and has set the initial coefficient K_{RP} at 0.2 hPa per minute (hPa/mn). The physician also set that when a snoring is detected K_E equals 1 hPa when the breath rate is below a set threshold.

When the apparatus starts the control units supply the blower in order to set at the patient's mask a pressure of 4 hPa. After 2 minutes, the ramp module starts increasing the value P_M . As no events occurs, the coefficient K_{RP} stays at 0.2 hPa. After 10 minutes the value P_M is of 5.6 hPa (8 minutes multiplied by 0.2 hPa/mn and added to the 4 hPa). After these ten minutes, the patient's breath is below threshold. The ramp module adds the corresponding K_B value to the coefficient K_{RP} , which thus equals 1.2 hPa/mn. The treatment pressure is thus raised in about 13 minutes and 40 seconds.

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CLAIMS

- 1. An apparatus (1) to assist a patient respiration by delivering air to a patient trough a mask (20), comprising:
- 5 a blower (4) to provide the patient with air under a treatment pressure,
 - a control unit (2) to adjust the pressure delivered by said blower at the level of said mask,
 - a ramp module (10) connected to the control unit in order to provide the control unit with the value of pressure P_M to settle at said mask, so that when said apparatus starts functioning, the pressure progressively rises until the pressure of treatment P_T ;
 - characterized in that it comprises a comparator connected to the ramp module, at least one means for detecting the patient's breathing parameters and sending them to said comparator, in order in response to said breathing parameters, that the comparator is able to determine that an event $(E_1, E_2 \text{ or } E_3)$ occurs in patient's breathing and to send the corresponding data to the ramp module which provides the control unit with a value of pressure P_M that will speed up with respect of time, so that the rise of pressure at patient's mask is accelerated.
- 2. The apparatus (1) according to claim 1, wherein said ramp module provides the value of pressure P_M being a linear function of time wherein the increase coefficient K_{RP} is constant, said ramp module increasing that coefficient of a constant value K_E when the control unit (2) send a data corresponding to said event $(E_1, E_2 \text{ or } E_3)$.
 - 3. The apparatus according claim 1 or 2, wherein the value of pressure P_M has always maximum and/or minimum limits so that the increase of pressure is also limited in minimum and/or maximum.

- 4. The apparatus according claim 2 and 3, wherein said ramp module (10) comprises a memory (12) where a minimum coefficient K_{SRP} is stored, said ramp module always maintaining the coefficient K_{RP} equal or superior to said minimum coefficient K_{SRP} , so that the ramp module provides the control unit (2) with a value of pressure P_M always superior to a minimum limit.
- 5. The apparatus (1) according to claim 2 and 3, wherein said ramp module (10) comprises a memory (12) where a maximum coefficient K_{MRP} is stored, said ramp module always maintaining the coefficient K_{RP} equal or inferior to said maximum coefficient K_{MRP} , so that the ramp module provides the control unit (2) with a value of pressure P_M always inferior to a maximum limit.
 - 6. The apparatus according to any of the previous claims, wherein said means (6) for detecting the patient's breathing parameters enable the control unit (2) to compute the airflow at patient's mask (20), said comparator determining that an event $(E_1, E_2 \text{ or } E_3)$ is occurring with the airflow parameters or shape.
- 7. The apparatus according to any one of the previous claims, wherein the ramp module (10) increases the value of pressure P_M when an anomaly, such as snoring or apnea, in patient's breathing is detected.
- 8. The apparatus according to any one of the previous claims, wherein the ramp module (10) increases the value of pressure P_M when the patient's breathing parameters correspond to a drop between awake breathing and asleep breathing or when they correspond to a stable frequency of breathing.

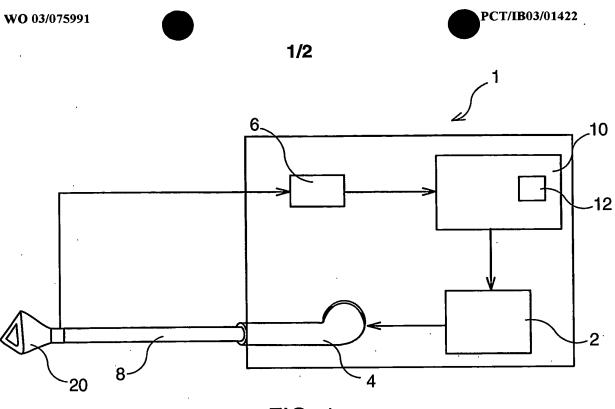


FIG. 1

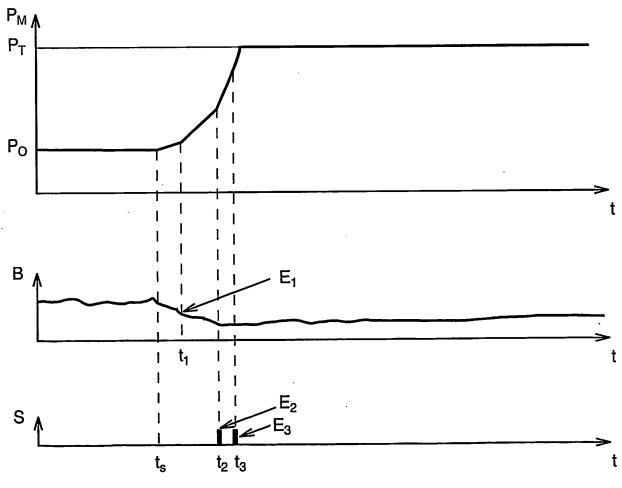
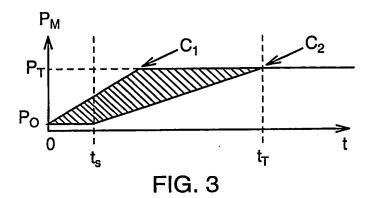


FIG. 2



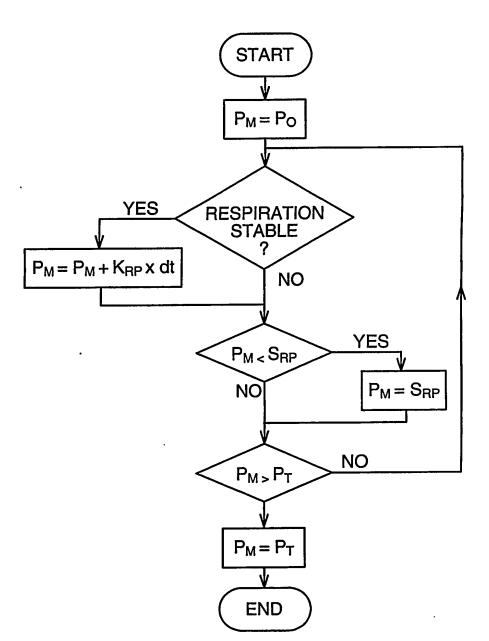


FIG. 4



INTERNATIONAL SEARCH REPORT

Inte anal Application No PCT/IB 03/01422

A. CLASSIF IPC 7	A61M16/00			
According to	International Patent Classification (IPC) or to both national classific	ation and IPC		
B. FIELDS				
Minimum dod IPC 7	cumentation searched (classification system followed by classificat $A61M$	ion symbols)		
4	ion searched other than minimum documentation to the extent that			
Electronic da EPO-In	ata base consulted during the International search (name of data b	ase and, where practical, search terms used)		
C. DOCUME	ENTS CONSIDERED TO BE RELEVANT			
Category °	Citation of document, with indication, where appropriate, of the r	elevant passages	Relevant to claim No.	
X	US 5 970 975 A (ESTES MARK C ET 26 October 1999 (1999-10-26) cited in the application column 1, line 13 - line 22 column 6, line 62 - line 65 column 18, line 57 -column 19, column 21, line 53 -column 23, column 23, line 54 -column 24, column 24, line 62 -column 28, claims 2-5; figures 1,2,5-6,8A-US 5 245 995 A (LYNCH CHRISTOPH 21 September 1993 (1993-09-21) column 2, line 56 - line 61 column 5, line 22 - line 34	1-8		
	column 6, line 54 -column 7, 11	ne 61 -/		
X Fur	ther documents are listed in the continuation of box C.	X Patent family members are lister	d in annex.	
Special categories of cited documents: A document defining the general state of the art which is not considered to be of particular relevance E earlier document but published on or after the international filing date L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) O document referring to an oral disclosure, use, exhibition or other means		To later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention. It document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone. It document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.		
<u> </u>	e actual completion of the international search	Date of mailing of the international s	earch report	
	16 June 2003	03/07/2003		
Name and	d mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tol (191-70) 340-2040 Tx, 31 651 epp ni.	Authorized officer		
	Tel. (+31-70) 340-2040, Tx. 31 651 epo n1, Fax: (+31-70) 340-3016	Borowski, A		

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INTERNATIONAL-SEARCH REPORT

Inte al Application No
PCT/IB 03/01422

C.(Continual	tion) DOCUMENTS CONSIDERED TO BE RELEVANT	
Category °	Citation of document, with Indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 503 146 A (FROEHLICH JAMES P ET AL) 2 April 1996 (1996-04-02) column 1, line 6-10 column 1, line 54 -column 2, line 14 column 2, line 34 - line 65 column 3, line 52 -column 5, line 40 claims 1,2; figures 1,2	1-8



Inte _ nal Application No PCT/IB 03/01422

Patent document dted in search report		Publication date		Patent family member(s)		Publication date
US 5970975	A	26-10-1999	US	5551418	A	03-09-1996
			US	5239995 <i>l</i>	A	31-08-1993
			US	5901704 /	A	11-05-1999
			US	5904141	A	18-05-1999
			US	· 5823187 /	A	20-10-1998
			ΑT	10001	T	15-01-2000
			AU	660340 I	B2	22-06-1995
			AU	2926892 <i>l</i>	A	07 - 06-1993
			CA		A1	13-05-1993
			DE		D1	17 - 02-2000
			DE		T2	31-08-2000
			EP	0610405 /		17-08-1994
			US	V	B1	06-08-2002
			WO	9308857 /	A1	13-05-1993
			US	5492113 /		20-02-1996
			US	RE35295 I	E 	16-07-1996
US 5245995	Α	21-09-1993	US	2002124848	A 1	12-09-2002
			US	2002100477	A 1	01-08-2002
			US	6398739 1	B1	04-06-2002
			US		A	04-06-1996
			US	5199424		06-04-1993
			US	2002007127	A1	17-01-2002
US 5503146	Α	02-04-1996	AU	689641	 В2	02-04-1998
			ΑU	3435495	Α	09-05-1996
			BR	9504560	Α	25-02-1997
			CA	2160509		27-04-1996
			EP	0709107	A 1	01-05-1996